K982196

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201-0414

OCT 6 1998

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Pat 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: 19 June, 1998

Identification of Product: Digital Radiographic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices: The SG60 vertical wallstand was pre-Amendment and the SCX radiographic system was introduced in 1986 (K862120). Subsequently, these were used with the Ultranet-SA Collimator (K894142), the Maxiray 100 Radiographic Tube (K812915), and the SCPU Generator (K940277).

Device Description: The Digital Radiographic Imaging System is designed to perform radiographic examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing and storage. The Digital Radiographic Imaging System consists of a wallstand, tubestand, x-ray tube, collimator, system controller, generator and digital detector.

Indications for Use: The Digital Radiographic Imaging System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film / screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Comparison with Predicate:

It is the opinion of GE Medical Systems that the Digital Radiographic Imaging System is of comparable type and substantially equivalent to the Advantx Radiographic System (originally cleared as the SCX K862120) combined with a SG-60 vertical wallstand with respect to intended use, radiation characteristics and image quality. The Digital Radiographic Imaging System presents no new safety concerns. It will comply with the x-ray requirements of 21CFR as well as safety requirements of UL2601-1, IEC601-1 and collateral standards.

Summary of Studies:

Two radiologists at each of three hospitals evaluated 30 paired digital and film / screen images of representative anatomical areas, and found that the digital images had equivalent or better image quality.

Conclusions:

GE considers the Digital Radiographic Imaging System to be equivalent with the predicate device. Digital Radiographic Imaging System provides radiograms that result in equivalent or better imaging performance than film / screen images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- A Hazard Analysis
- A Software Development and Validation Process
- External validations of paired sets of film / screen image and digital images by three different research hospitals to assess the diagnostic equivalence of the digital images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1998

Larry Kroger
Senior Regulatory Programs Manager
General Electric Company
PO Box 414
Milwaukee, WI 53201

Re: K982196
GE Digital Radiographic Imaging System
Dated: September 4, 1998
Received: September 8, 1998
Regulatory class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Mr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K982196

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982196